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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/064,859

08/23/2002

Peter Fletcher-Haynes

BC-0233-US04

4599

24994

7590

09/23/2004

GAMBRO, INC  
PATENT DEPARTMENT  
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EXAMINER

GUTIERREZ, ANTHONY

ART UNIT

PAPER NUMBER

2857

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/064,859

Applicant(s)

FLETCHER-HAYNES ET AL.

Examiner

Anthony Gutierrez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 35-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Stacey et al. (US Patent 5,769,811).

As to claim 35, Stacey et al. discloses a method for data entry into a blood processing machine (col. 7, lines 14-33), comprising the steps of: scanning barcode data into the blood processing machine via a barcode reader connected to the blood processing machine in data communication relationship therewith (col. 7, lines 34-54); assigning the scanned barcode data to a particular blood processing category relative to a particular blood processing procedure (col. 7, lines 48-50); and using the assigned scanned barcode data in the management of at least one blood processing procedure (col. 11, lines 17-28).

As to claim 36, Stacey et al. discloses biological data relating to a source of whole blood (col. 5, lines 3-9).

As to claim 37, Stacey et al. discloses supply data relating to a supply for use in a blood processing procedure (col. 5, lines 10-12).

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As to claims 38 and 39, Stacey et al. discloses storing the data in a central database (col. 2, lines 47-62).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-14, 17-20, and 22-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urdahl et al. (US Patent 5,658,240) in view of Gilcher et al. (US Patent 6,113,554).

As to claims 1-7, 10-14, 18-20, 22-28, 30, Urdahl et al. discloses a method for collecting at least one predetermined type of blood component from a source of whole blood using a blood component collection system comprising a blood component collection device and a collection procedure, said collection procedure having a plurality of control parameters associated therewith (Abstract), said method comprising the steps of: providing biological data relating to said source of whole blood (col. 2, lines 56-60); obtaining historical data from a centralized location (col. 2, lines 61-63); identifying at least one of a desired yield of said at least one predetermined blood component or a time period for duration of the collection procedure (col. 2, line 64- col. 3, line 21); performing a first deriving step comprising deriving a magnitude for at least one

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of said control parameters from at least two of said providing, obtaining and identifying step (col. 8, line 65 to col. 9, line 34); using said magnitude of said at least one of said control parameters obtained during said first deriving step to control the operation of said blood component collection system (col. 9, lines 35-55); and performing said collection procedure on said blood component collection device using said at least one of said control parameters obtained during said first deriving step to control at least one of the collection of said desired yield of said at least one predetermined blood component from said source of whole blood or the time period of duration of said collection procedure, thereby providing optimizations (col. 23, lines 21-34).

Urdahl et al. discloses a centralized location, in a whole blood collection system, for handling donor historical data, procedural data, and run data as addressed above and in col. 5, lines 6-40). It is in the form of a central input station such as an IBM compatible PC and attendant software (col. 5, lines 6-8).

Urdahl et al. does not specifically disclose the use of a database.

Gilcher et al., however, discloses using a database in a whole blood collection system (Title) for collecting and retrieving donor historical data, procedural, and run data (col. 9, line 35-col. 10, line 54). Gilcher et al. teaches that such a database allows for necessary correlation between a donor's information and the blood collected (col. 10, lines 24-33) and facilitates later retrieval and analysis (col. 10, lines 51-54).

It therefore would have been obvious to one of ordinary skill in the art at the time of invention to implement a database, as taught by Gilcher et al. at the central input station of Urdahl et al. in order to bypass the use of time consuming

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manual entry of data and possible human error, thereby benefiting from the ability to properly correlate data and easily retrieve it.

As to claim 8, Urdahl et al. discloses stored run data that includes blood component loss data (col. 25, lines 34 and 49).

As to claim 9, Urdahl et al. discloses stored run data that includes donation interval data (col. 25, lines 1 and 21).

As to claims 17, 29, 31, and 32, both references finalize the procedure by generating written reports (Urdahl et al.- col. 24, lines 34-47; Gilcher et al. -col. 10, lines 46-65).

5. Claims 15, 16, 21, and 40-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urdahl et al. (US Patent 5,658,240) in view of Gilcher et al. (US Patent 6,113,554), further in view of Stacey et al. (US Patent 5,769,811).

The combination of Urdahl et al. and Gilcher et al. discloses a centralized location, in a whole blood collection system, for handling donor historical data, procedural data, and run data, including the use of a centralized database as addressed above.

Neither reference specifically teaches the use of a bar-code reader for data communication in the blood processing environment.

Stacey et al., however, teaches the use of a bar-code reader in a blood processing environment, as addressed above, and specifically teaches that it is a preferred method for data communication with respect to convenience and economy (col. 7, lines 34-65).

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It therefore would have been obvious to one of ordinary skill in the art at the time of invention to use a bar-code reader for data communication, as taught by Stacey et al., in the blood processing environment as disclosed by Urdahl et al. and Gilcher et al., in order quickly and accurately process and verify data related to extracorporeal blood processing.

6. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urdahl et al. (US Patent 5,658,240) in view of Gilcher et al. (US Patent 6,113,554), further in view of Poulsen et al. (US Patent 6,656,114 B1).

The combination of Urdahl et al. and Gilcher et al. discloses a centralized location, in a whole blood collection system, for handling donor historical data, procedural data, and run data, including the use of a centralized database as addressed above.

Neither reference specifically teaches the use of wireless communication subsystem or orbital satellite communications equipment.

Poulsen et al., however, teaches a system for communicating information regarding a patient's medical record from a central server that includes a wireless local area network, and a satellite link (col. 16, lines 20-59). These features allow the system to provide warnings or alarms and to facilitate time efficient communication (col. 16, lines 53-59).

It therefore would have been obvious to one of ordinary skill in the art at the time of invention to incorporate wireless and satellite communication equipment, as taught by Poulsen et al. into the centralized database of the combination of Urdahl et al. and Gilcher et al., which includes donor historical

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data, in order to access and submit donor data to the centralized database more rapidly, with less effort, and in order to provide the database with the most up to date data as frequently as possible.

### ***Double Patenting***

7. Claims 1-34, and 40-45 of this application conflict with claims 1, 3, 4, 6, and 8-29 of Application No. 09/797,325.

37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

8. Claims 1-14, 17-20, and 22-32, are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3, 4, 6, and 8-29 of copending Application No. 09/797,325. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

9. Claims 15, 16, 21, and 40-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 16 of copending Application No. 09/797,325, in view of Stacey



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et al. (US Patent 5,769,811). This is a provisional obviousness-type double patenting rejection.

Claims 1 and 16 of copending Application No. 09/797,325 are directed to a centralized location in a whole blood collection system, for handling donor historical data, procedural data, and run data, including the use of a centralized database as addressed above.

The claims do no mention the use of a bar-code reader for data communication in a blood processing environment.

Stacey et al., however, teaches the use of a bar-code reader in a blood processing environment, as addressed above, and specifically teaches that it is a preferred method for data communication with respect to convenience and economy (col. 7, lines 34-65).

It therefore would have been obvious to one of ordinary skill in the art at the time of invention to use a bar-code reader for data communication, as taught by Stacey et al., in the blood processing environment as claimed in claims 1 and 16 of the copending application in order quickly and accurately process and verify data related to extracorporeal blood processing.

10. Claims 33 and 34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of copending Application No. 09/797,325, in view of Poulsen et al. (US Patent 6,656,114 B1). This is a provisional obviousness-type double patenting rejection.

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Claim 1 of copending Application No. 09/797,325 is directed to a centralized location in a whole blood collection system, for handling donor historical data, procedural data, and run data, including the use of a centralized database as addressed above.

The claim does not mention the use of wireless or satellite communication systems or equipment.

Poulsen et al., however, teaches a system for communicating information regarding a patient's medical record from a central server that includes a wireless local area network, and a satellite link (col. 16, lines 20-59). These features allow the system to provide warnings or alarms and to facilitate time efficient communication (col. 16, lines 53-59).

It therefore would have been obvious to one of ordinary skill in the art at the time of invention to incorporate wireless and satellite communication equipment, as taught by Poulsen et al. into the centralized database of the combination of Urdahl et al. and Gilcher et al., which includes donor historical data, in order to access and submit donor data to the centralized database more rapidly, with less effort, and in order to provide the database with the most up to date data as frequently as possible.

**Conclusion**

11. If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate that the copy was not readily available, it is because the copy could not be readily obtained when the Office action was mailed. Should applicant desire a copy of such a provisional application, applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Gutierrez whose telephone number is (571) 272-2215. The examiner can normally be reached on Monday to Friday.

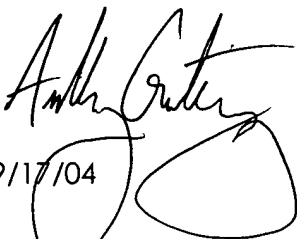
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc Hoff can be reached on (571) 272-2216. The fax


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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anthony Gutierrez

  
9/17/04

  
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